



ATTORNEY DOCKET No.: 2003946-0080 (FP04-0096-00US-XX)

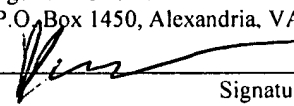
**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: Yamamoto, et. al.  
Serial No: 10/797,903  
Filing Date: March 10, 2004  
Priority Appln. No.: JP 2003-062823; filed: March 10, 2003  
JP 2003-302803; filed: August 27, 2003  
Title: c-KIT KINASE INHIBITOR

Examiner: NYA  
Group Art Unit: 3612

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

<b>Certificate of Mailing</b>	
I certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450	
March 3, 2006	
Date	Signature
Mary Wilson	
Typed or Printed Name of person signing certificate	

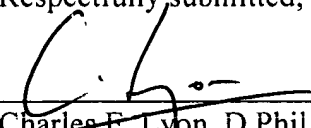
**TRANSMITTAL LETTER**

Enclosed herewith please find the documents listed below:

1. Copy of the English Translation of the International Preliminary Report on Patentability (Chapter 1) issued in PCT/JP2004/003087 (6 pages); and
2. Return Post Card.

Dated: March 3, 2006

Respectfully submitted,

  
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From the INTERNATIONAL BUREAU

**PCT**

NOTIFICATION OF TRANSMITTAL  
OF COPIES OF TRANSLATION  
OF THE INTERNATIONAL PRELIMINARY REPORT  
ON PATENTABILITY  
(CHAPTER I OR CHAPTER II  
OF THE PATENT COOPERATION TREATY)  
(PCT Rules 44bis.3(c) and 72.2)

To:

HASEGAWA, Yoshiki  
Soei Patent and Law Firm  
Ginza First Bldg.  
10-6, Ginza 1-chome  
Chuo-ku, Tokyo 1040061  
JAPON

Date of mailing (day/month/year)

23 February 2006 (23.02.2006)

Applicant's or agent's file reference  
FP04-0096-00**IMPORTANT NOTIFICATION**International application No.  
PCT/JP2004/003087International filing date (day/month/year)  
10 March 2004 (10.03.2004)

Applicant

EISAI CO., LTD. et al

**1. Transmittal of the translation to the applicant.**

The International Bureau transmits herewith a copy of the English translation of the international preliminary report on patentability (Chapter I).



The International Bureau transmits herewith a copy of the English translation of the international preliminary report on patentability (Chapter II).

**2. Transmittal of the copy of the translation to the designated or elected Offices.**

The International Bureau notifies the applicant that copies of that translation have been transmitted to the following designated or elected Offices requiring such translation:

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The following designated or elected Offices, having waived the requirement for such a transmittal at this time, will receive copies of that translation from the International Bureau only upon their request:

AE, AG, AL, AM, AP, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EA, EC, EE, EG, EP, ES, FI, GB, GD, GE, GH, GM, GR, GU, HD, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OA, OM, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW

**3. Reminder regarding translation into (one of) the official language(s) of the elected Office(s).**

The applicant is reminded that, where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary report on patentability (Chapter II).

It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned within the applicable time limit (Rule 74.1). See Volume II of the PCT Applicant's Guide for further details.

The International Bureau of WIPO  
34, chemin des Colombettes  
1211 Geneva 20, Switzerland

Authorized officer

Masashi Honda

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## PATENT COOPERATION TREATY

## PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY  
(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference FP04-0096-00	FOR FURTHER ACTION		See item 4 below
International application No. PCT/JP2004/003087	International filing date ( <i>day/month/year</i> ) 10 March 2004 (10.03.2004)	Priority date ( <i>day/month/year</i> ) 10 March 2003 (10.03.2003)	
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237			
Applicant EISAI CO., LTD.			

- This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 bis.1(a).
- This REPORT consists of a total of 5 sheets, including this cover sheet.  
  
In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.
- This report contains indications relating to the following items:
 

<input checked="" type="checkbox"/> Box No. I	Basis of the report
<input type="checkbox"/> Box No. II	Priority
<input type="checkbox"/> Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
<input type="checkbox"/> Box No. IV	Lack of unity of invention
<input checked="" type="checkbox"/> Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
<input checked="" type="checkbox"/> Box No. VI	Certain documents cited
<input type="checkbox"/> Box No. VII	Certain defects in the international application
<input type="checkbox"/> Box No. VIII	Certain observations on the international application
- The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland  Facsimile No. +41 22 740 14 35	Date of issuance of this report 13 February 2006 (13.02.2006)
	Authorized officer  Masashi Honda  Telephone No. +41 22 338 70 10

## PATENT COOPERATION TREATY

From the  
INTERNATIONAL SEARCHING AUTHORITY

PCT

Translation

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

To:		Date of mailing (day-month-year)	
Applicant's or agent's file reference <b>FP04-0096-00</b>		FOR FURTHER ACTION See paragraph 2 below	
International application No. <b>PCT/JP2004/003087</b>	International filing date (day-month-year) <b>10.03.2004</b>	Priority date (day-month-year) <b>10.03.2003</b>	
International Patent Classification (IPC) or both national classification and IPC			
Applicant <b>EISAI CO., LTD.</b>			

## 1. This opinion contains indications relating to the following items:

- |                                     |              |  |
|-------------------------------------|--------------|--|
| <input checked="" type="checkbox"/> | Box No. I    | Basis of the opinion   |
| <input type="checkbox"/>            | Box No. II   | Priority   |
| <input type="checkbox"/>            | Box No. III  | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability   |
| <input type="checkbox"/>            | Box No. IV   | Lack of unity of invention   |
| <input checked="" type="checkbox"/> | Box No. V    | Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability, citations and explanations supporting such statement |
| <input checked="" type="checkbox"/> | Box No. VI   | Certain documents cited  |
| <input type="checkbox"/>            | Box No. VII  | Certain defects in the international application   |
| <input type="checkbox"/>            | Box No. VIII | Certain observations on the international application  |

## 2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

## 3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/JP	Authorized officer
Facsimile No.	Telephone No.

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/JP2004/003087

Box No. I

Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This opinion has been established on the basis of a translation from the original language into the following language \_\_\_\_\_, which is the language of a translation furnished for the purposes of international search (under Rule 12.3 and 23.1(b)).
2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
- a. type of material
- ☐ a sequence listing
- ☐ table(s) related to the sequence listing
- b. format of material
- ☐ in written format
- ☐ in computer readable form
- c. time of filing/furnishing
- ☐ contained in the international application as filed.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/JP2004/003087

Box No. V	Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement		
<b>1. Statement</b>			
Novelty (N)	Claims		YES
	Claims	1-15	NO
Inventive step (IS)	Claims		YES
	Claims	1-15	NO
Industrial applicability (IA)	Claims	1-15	YES
	Claims		NO
<b>2. Citations and explanations:</b>			
(Documents)			
1. WO 02/032872 A1 (Eizai Co., Ltd.), 25 April, 2002 (25.04.02)			
2. WO 00/43366 A1 (KIRIN BREWERY CO., LTD.), 27 July, 2000, (27.07.00)			
3. WO 2004/039782 A1 (KIRIN BREWERY CO., LTD.), 13 May, 2004 (13.05.04)			
(Explanations)			
<u>Concerning claims 1-10 and 12-14:</u>			
<p>The inventions disclosed in claims 1-10 and 12-14 do not appear to be novel or to involve an inventive step on account of document 1 cited in the ISR. Document 1 discloses that compounds represented by the general formula I described in claim 1 of the present application are effective as an anticancer agent, an angioma remedy, a cancer innidation inhibitor and a drug for curing inflammatory affection caused by delayed irritation. Also, it is disclosed in the specification of the present application that the c-Kit kinase inhibitor of the present application is effective as a drug for curing various tumors, allergy and asthma, so that the inventions disclosed in claims 1-10 and 12-14 cannot be held to be different from the inventions disclosures in document 1.</p>			
<p>Furthermore, the inventions disclosed in claims 1-10 and 12-14 do not appear to involve an inventive step on account of document 2 cited in the ISR. Document 2 discloses that compounds with similar structures as those of compounds represented by the general formula I described in claim 1 of the present application are effective as an anticancer agent, etc. Also, it is usual practices in the field of medicine to modify structures of pharmacologically active compounds as one thinks fit, so that it is obvious for a person skilled in the art to examine anticancer activity of compounds disclosed in document 2 by changing, as one thinks fit, a substituent in the 6<sup>th</sup> or 7<sup>th</sup> position etc. on the quinoline ring of which various alternatives are described.</p>			
<u>Concerning claims 11 and 15:</u>			
<p>The inventions disclosed in claims 11 and 15 do not appear to be novel or to involve an inventive step on account of document 1 cited in the ISR. Document 1 discloses that compounds represented by the general formula I described in claim 1 of the present application are effective as a drug for curing inflammatory affections caused by delayed irritation and other drugs, and it can be considered that allergy and asthma, etc. correspond to inflammatory affections caused by delayed irritation.</p>			

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/JP2004/003087

## Box No. VI Certain documents cited

## 1. Certain published documents (Rule 43bis.1 and 70.10)

Application No. Patent No.	Publication date (day month year)	Filing date (day month year)	Priority date (valid claim) (day month year)
WO 2004/039782 A1 [EX]	13.05.2004	29.10.2003	29.10.2002

## 2. Non-written disclosures (Rule 43bis.1 and 70.9)

Kind of non-written disclosure

Date of non-written disclosure  
(day month year)Date of written disclosure  
referring to non-written disclosure  
(day month year)